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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Juha Voipio

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7857

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7590

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/727,511	Applicant(s) VOPIO ET AL.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The examiner acknowledges the amendments received 15 June 2006. Claims 1-13 are pending.

#### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 15 June 2006 have been fully considered but they are not persuasive. The applicant argues that the Renirie et al (U.S. 6,141,590) reference applied in the last Office Action did not include all of the claimed elements, specifically (page 7, "Remarks") "Renirie does not disclose monitoring respiration as respiration correlates to the VNS intensity." The applicant goes on to state that instead "Renirie monitors respiration as an independent parameter to determine when cardiac pacing should be performed. Thus, the problem solved by Renirie is completely different from the problem to be solved by the present invention with respect to central nervous system." The examiner respectfully disagrees. Renirie discloses (col. 3, lines 60-64) "A respiration sensor obtains respiration signals representative of the amplitude and timing of patient respiration, which are used for developing rate modulation signals for controlling delivery of stimulation pulses." Renirie also states that these stimulation pulses may be directed to the patient's heart, or to the vagus nerve or parasympathetic nervous system (col. 4, lines 5-8). The respiration parameters therefore do have a relationship to the VNS intensity. With regards to the arguments concerning claim 7,

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the examiner would like to point out Renirie (col. 3, lines 56-59), in which it is stated "a system for respiration-modulated pacing, providing rate control for controlling the rate of generating and delivering stimulus pulses to correspond to the sensed inspiration and expiration phases of the patient's respiratory cycle." This is a clear indication that the vagal stimulation does in fact modulate breathing, and regulating stimulation intensity in response to a respiratory parameter.

4. In response to applicant's arguments, it is to be noted that the recitation "the central nervous system affecting vagal nerve stimulation (VNS)" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). This applies both to Renirie and to Obel et al (U.S. 5,199,428), which was also used in the previous Office Action.

5. In further regards to Obel, the examiner would like to reiterate the citation of the previous Office Action, that Obel discloses (col. 3, lines 15-25) a method to "ameliorate myocardial ischemia and maintain adequate cardiac rate through stimulation of the vagal nervous system (or other effective nerves) as well as the heart tissue in a concerted fashion dependent upon need as automatically determined by the system." This is accomplished by "comparison of the patient's coronary sinus blood pH and/or

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oxygen saturation and/or electrocardiogram ST elevation to preset, normal threshold and triggering burst stimulation of the nerves until the blood gas and/or ST segment variations have been returned to non-clinical risk levels.” This clearly states that respiration parameters have a direct effect on the intensity of the stimulation applied to the nerves.

6. For these reasons, the rejections of claims 1-3, 5, 8-10 and 12 under 35 U.S.C. 102(b) are maintained.

7. Claims 1-2, 5, 8-9 and 12 stand rejected under 35 U.S.C. 102(b) as being anticipated by Renirie et al (U.S. 6,141,590). Claims 1, 3, 8 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al (U.S. 5,199,428). For a full discussion of the claimed material, see the previous Office Action dated 15 March 2006.

### ***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Applicant's arguments filed 15 June 2006 have been fully considered but they are not persuasive. The examiner directs attention to the above response to arguments (“Claim Rejections –35 USC § 102”). The rejections of claims 4, 6-7, 11 and 13 under 35 U.S.C 103(a) are maintained.

10. Claims 4, 6-7, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al (U.S. 6, 141,590).

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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